

## State of New Hampshire DEPARTMENT OF ENVIRONMENTAL SERVICES

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January 22, 1999

Ms. Linda L. Baetz, Program Manager
Hazardous and Medical Waste
Department of the Army
U.S. Army Center for Health Promotion and Preventive Medicine
5158 Blackhawk Road
Aberdeen Proving Ground, Maryland 21010-5422

SUBJECT: HAZARDOUS WASTE REGULATORY STATUS OF PHARMACEUTICALS

Dear Ms. Baetz:

The New Hampshire Department of Environmental Services, Waste Management Division has received your letter dated June 29, 1998 requesting an interpretation of the hazardous waste regulatory status of returned, expired pharmaceuticals. Based upon a review of the information in your letter and the New Hampshire Hazardous Waste Rules (Env-Wm 100-1000), we offer the following:

As we understand the situation, Army medical centers throughout the country stock various pharmaceuticals that are dispensed to patients. Some of these items, once expired, have the potential to be classified as hazardous waste due to the fact that they meet the statutory definition of a "waste", and are either listed or are characteristic hazardous wastes. Currently, the Army has stressed the return of pharmaceuticals, which have the potential to be hazardous waste, to either the manufacturer or a third party service company, before the expiration of the item. Pharmaceuticals are returned for many reasons including oversupply, recall, and expiration of the product. If the item is expired, then the item is currently managed as a hazardous waste from the individual Army facility. In your letter, you request that Army medical centers be allowed to return all expired pharmaceuticals to a third party service company which facilitates the handling, crediting, and, if needed, the appropriate disposal of the returned pharmaceuticals. Once received, this company will then determine whether the returned item will be reused, reclaimed, sold, destroyed, or disposed of, and, as such, this company would be the generator of record for the waste if the item is to be disposed. Your letter asks for our regulatory interpretation of this proposal.

Env-Wm 502.01 of the New Hampshire Hazardous Waste Rules requires that all generators of a waste shall determine if that waste is a hazardous waste. To the extent that the returned pharmaceuticals are expired (i.e., a "waste"), and are listed or characteristic hazardous wastes, then the pharmaceuticals would be regulated as hazardous wastes. The requirements for the recycling of hazardous waste are set forth in Chapter Env-Wm 800 of the Hazardous Waste Rules. Env-Wm 803.04(a) specifically states:

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"....a material shall not be deemed to be a waste when it can be shown to be recycled by being: ....

(2) Used or reused as an effective substitute for commercial products, provided the material is not being reclaimed;"

We believe that the Army medical centers would need to have a reasonable expectation, and be able to document, that the expired pharmaceuticals will be recycled by being used or reused as an effective substitute for commercial products rather than disposed. If this is the case, the items would meet the classification of "not a waste when recycled" as stated in Env-Wm 803.04. As such and as far as the State of New Hampshire is concerned, the Army medical centers would not need to use a hazardous waste manifest or use a registered New Hampshire Hazardous Waste transporter to deliver the pharmaceuticals to the third party service company, but would remain subject to any applicable U.S Department of Transportation or New Hampshire Department of Safety transportation regulations.

Despite the fact that these returned pharmaceuticals are not subject to regulation under the State of New Hampshire Hazardous Waste Rules when recycled by being used or reused as effective substitutes for commercial products, the Army medical centers should ensure that storage and handling practices for the materials do not pose a hazard to human health or the environment (i.e., are consistent with other provisions of law that are protective of groundwater, surface water, and air). Please be advised that in situations where the Army medical centers definitely know that the returned pharmaceuticals will be destroyed or disposed of, then the items would need to be managed as hazardous waste from the individual Army facility.

If you have any questions regarding this matter, please feel free to call Tod G. Leedberg, Waste Management Specialist, or me at (603)271-2942.

Sincerely,

John J. Duclos, Supervisor Hazardous Waste Compliance Section Waste Management Division

ce: DB/STATE/RPB
Edward K. McSweeney, EPA
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Richard Reed, WMD-SWMB
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armypharm.821

following is a list of RCRA-hazardous drugs and their EPA hazardous waste numbers. This is not inclusive of all agents as there are new products being developed:

Product	EPA#
Product	
CYTOTOXICS	11015
Azaserine	U015
Chlorambucil (Leukeran)	U035
Cyclophosphamide (Cytoxan, CTX)	U058
Chlornaphazin	U026
Daunomycin (Daunorubicin)	U059
3,3'-Dichlorobenzidine	U073
Diethylstilbestrol (DES)	U089
3,3-Dimethoxybenzidine	U091
p-Dimethylaminoazobenzene	U093
Ethylene Thiourea	U116
Maleic Hydrazine (Maleic Hydrazide)	U148
Melphalan (Alkeran)	U150
4,4-Methylene Bis (2-chloroaniline)	U158
Mitomycin-C Mutamycin)	U010
1-Naphthalenamine	U167
Streptozocin (Zanosar, SZNO)	U206
O-tolidine	U328
Uracil Mustard	U237
OTHER	P042
Epinephrine	D001
Iodine Tincture	D001
Kit Antidote Treatment Cyanide	P042
Kit Insect Sting	P081
Nitroglycerin	P208
Physostigmine	P188
Physostigmine Salicylate	U129
Shampoo with Benzene Hexachloride	D013
Shampoo with Lindane	U035
Chlorambucil	P001
Warfarin Sodium	P001